UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,439	08/19/2005	Thomas Hesterkamp	2335.0020001/SRL/KPQ	9959

26694 7590 12/13/2007

VENABLE LLP
P.O. BOX 34385
WASHINGTON, DC 20043-9998

EXAMINER	
DUTT, ADITI	

ART UNIT	PAPER NUMBER
1649	

MAIL DATE	DELIVERY MODE
12/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/517,439	HESTERKAMP ET AL.	
	Examiner	Art Unit	
	Aditi Dutt	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-24* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-2, 10, 12, 19, drawn to a method of diagnosing or prognosticating a neurodegenerative disease in a subject, comprising determining the level or activity of a transcription or a translation product or fragments thereof, corresponding to a steroidogenic acute regulatory protein (Star) in a sample of the subject.

Group II, claim(s) 3, 13, drawn to a kit for diagnosing or prognosticating a neurodegenerative disease in a subject, comprising reagents for selective detection of a transcription or a translation product, corresponding to a steroidogenic acute regulatory protein (Star).

Group III, claim(s) 4, drawn to a modulator of an activity and/or level of a transcription or a translation product or fragments thereof, corresponding to a steroidogenic acute regulatory protein (Star).

Group IV, claim(s) 5, drawn to a recombinant non-human animal, comprising a gene coding for the steroidogenic acute regulatory protein or a fragment, variant, derivative thereof.

Group V, claim(s) 6, 11, 14, 20, drawn to a method of screening for a modulator of neurodegenerative diseases, corresponding to a transcription or a translation product or fragments thereof, of the steroidogenic acute regulatory protein (Star), by contacting a with a test compound.

Group VI, claim(s) 7-8, 15, 21-22, drawn to a method of screening for a modulator of neurodegenerative diseases, corresponding to a transcription or a translation product or

fragments thereof, of the steroidogenic acute regulatory protein (Star), by administering a test compound to a test animal.

Group VII, claim(s) 9, 16-17, 23-24, drawn to an assay for testing a compound for the inhibition of binding of binding between a ligand and a translation product of the gene encoding of the steroidogenic acute regulatory protein (Star).

2. The inventions listed as Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:
Group III recites the special technical feature of a modulator of an activity or level or activity of a transcription or a translation product or fragments thereof, corresponding to a steroidogenic acute regulatory protein, which is not required by the other products of Groups II and IV. Claim 4 is anticipated by prior art. Sugawara, et al. (PNAS 92: 4778-4782, 1995; abstract, page 4781, para 3; Figure 2) teach the regulation of Star mRNA levels by cAMP. Therefore, claim 4 lacks a special technical feature and cannot share one with the other claims.

Group I recites the special technical feature of diagnosing or prognosticating a neurodegenerative disease in a subject, comprising determining the level or activity of a transcription or a translation product or fragments thereof, corresponding to a steroidogenic acute regulatory protein in a sample of the subject, which is not required by the other methods of Groups V-VII.

Group II recites the special technical feature of a kit for diagnosing or prognosticating a neurodegenerative disease in a subject, comprising reagents for selective detection of a transcription or a translation product, corresponding to a steroidogenic acute regulatory protein, which is not required by the other products of Groups III and IV.

Group IV recites the special technical feature of a recombinant non-human animal, comprising a gene coding for the steroidogenic acute regulatory protein or a fragment, variant, derivative thereof, which is not required by the other products of Groups II and III.

Group V recites the special technical feature of screening for a modulator of neurodegenerative diseases, corresponding to a transcription or a translation product or fragments thereof, of the steroidogenic acute regulatory protein (Star), by contacting a with a test compound, which is not required by the other methods of Groups I, VI-VII.

Group VI recites the special technical feature of screening for a modulator of neurodegenerative diseases, corresponding to a transcription or a translation product or fragments thereof, of the steroidogenic acute regulatory protein (Star), by administering a test compound to a test animal, which is not required by the other methods of Groups I, V, VII.

Group VII recites the special technical feature of an assay for testing a compound for the inhibition of binding of binding between a ligand and a translation product of the gene encoding of the steroidogenic acute regulatory protein, which is not required by the other methods of Groups I, V-VI.

3. A further restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

The applicant is required to elect *one* product for prosecution, from one of the following groups:

A) Transcription product of steroidogenic acute regulatory protein or fragment, variant or derivative thereof

B) Translation product of steroidogenic acute regulatory protein or fragment, variant or derivative thereof

4. The inventions listed as Groups A-B do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: In the instant case, the different inventions of Groups (A-B) are unique nucleic acid and protein molecules of molecules and are composed of different nucleic acids or different amino acids.

Accordingly, each of the sequences are not so linked under PCT Rule 13.1 and are thus placed in two different inventive groups numbered A-B. Searching both the sequences in a single patent application would provide an undue search burden on the examiner and the USPTO's resources because of the non-coextensive nature of these searches. Furthermore, each of the sequences represents a gene or a protein with unique and diverse functional features and different classification.

Note: This is a Restriction requirement, not an Election of species. In order to be fully responsive, Applicant must select one from Inventions I-VII and one from groups A-B.

5. In response to this Office Action/Election requirement, applicant must elect one from Groups I-VII and A-B (gene or protein) for consideration.

6. Applicant is advised that in order for the reply to this requirement to complete it must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48 (b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. 1.48(b) and by the required under 37 C.F.R. 1.17(l).

Notice of Rejoinder

8. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

9. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised

that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Advisory Information

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aditi Dutt whose telephone number is 571-272-9037. The examiner can normally be reached on M-F.

11. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on 571-272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

12. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AD
23 November 2007

GARY B. NICKOL, PH.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600